REMARKS

Claims 1 – 8, 10, 12 – 16, 18 – 32 are currently pending. The currently pending independent claims are Claims 1, 18, 27, and 30 – 32.

In the current Office Action, Claims 1 – 8, 10, 12 – 13, 16 and 18 – 29 were rejected as allegedly obvious over U.S. Patent No. 6,039,974 to MacLaren et al. ("MacLaren") in view of U.S. Patent No. 4,695,467 to Uemura et al. ("Uemura") and U.S. Patent No. 5,858,412 to Staniforth et al. ("Staniforth"). In addition, Claim 30 was rejected as allegedly obvious over MacLaren taken in combination with Uemura, Staniforth, and U.S. Patent No. 5,164,193 to Okada et al. ("Okada"). Claims 14, 15, and 31 were rejected as allegedly obvious over MacLaren taken in combination with Uemura, Staniforth, and U.S. Patent No. 6,713,089 to Bertelsen et al. ("Bertelsen"). Finally, Claim 32 was rejected as allegedly obvious over MacLaren taken in combination with Uemura, Staniforth, Okada, and Bertelsen.

Each of the foregoing rejections is respectfully traversed and favorable reconsideration is requested in view of the above amendments and following remarks.

Applicants have amended independent Claims 1, 18, 27, and 31 to specify, *inter alia*, that the sustained release portion of the bilayer tablet includes (a) from about 10 wt. % to about 60 wt. % of a cellulose binder selected from the group consisting of hydroxypropyl methylcellulose, hydroxypropyl cellulose, and mixtures thereof, wherein the hydroxypropyl cellulose has a molecular weight of at least about 80,000; (b) from about 5 wt. % to about 50 wt. % of ethylcellulose; and (c) from about 10 wt. % to about 30 wt. % of a wax selected from the group consisting of stearyl alcohol, cetyl alcohol, carnauba wax, white wax, yellow wax, microcrystalline wax, and mixtures thereof.

Independent Claims 30 and 32 have also been amended to specify, *inter alia*, that the sustained release portion of the bilayer tablet includes (a) from about 10 wt. % to about 60 wt. % of hydroxypropyl methylcellulose; (b) from about 5 wt. % to about 50 wt. % of ethylcellulose; and (c) from about 10 wt. % to about 30 wt. % of stearyl alcohol.

The subject matter of these amendments is in no way suggested by the cited references, taken alone or in combination.

The Examiner once again takes MacLaren as his starting point and primary reference, but the MacLaren reference fails to disclose or suggest a sustained release portion of a bi-layer tablet including (a) from about 10 wt. % to about 60 wt. % of a cellulose binder selected from

the group consisting of hydroxypropyl methylcellulose, hydroxypropyl cellulose, and mixtures thereof, wherein the hydroxypropyl cellulose has a molecular weight of at least about 80,000; (b) from about 5 wt. % to about 50 wt. % of ethylcellulose; and (c) from about 10 wt. % to about 30 wt. % of a wax selected from the group consisting of stearyl alcohol, cetyl alcohol, carnauba wax, white wax, yellow wax, microcrystalline wax, and mixtures thereof. The Examiner concedes as much.

To overcome these deficiencies, the Examiner turns to Uemura and Staniforth. However, these references would not have led a person of ordinary skill in the art to formulate a bilayer tablet as called for in the present claims because, among other things, the information in MacLaren would have predisposed a person of ordinary skill against using a relatively small amount of wax in the order of 10 to 30 wt. % in a bilayer tablet formation.

The ingredients of a bilayer tablet are typically compressed not once, but twice, as discussed on page 3 of the Applicants' specification ("Such bilayer tablets are generally prepared by compressing a granulation onto a previously compressed granulation"). This makes the production and formulation of a bilayer tablet considerably more difficult than manufacture and formulation of a single layer tablet. The background of MacLaren testifies to many failed attempts to make workable bilayer tablets which combine antihistamines with sympathomimetic drugs such as decongestants. These are said to have failed due to unacceptable chemical degradation of the active ingredients and /or because the final bilayer tablet exhibited unacceptable cracking and physical strength properties. These materials are plainly thought to be very difficult to combine in distinct layers.

MacLaren specifically states that he was trying to overcome such difficulties and provide a bilayer tablet form "of high integrity … such that the tablet resists cracking on standing, has acceptable physical strength, and provides acceptable content uniformity which meets USP requirements." (Col. 2, lines 20 – 26). In order to do accomplish this in a bilayer tablet, MacLaren instructs, not once, but 3 times, that the extended release, decongestant part of the bilayer tablet should include from 59 to about 81 weight percent carnauba wax. (Col. 2, lines 62 – 63; Col. 3, lines 28 – 29; Col. 12, lines 1 – 4) His preferred amount is from 66 to about 74 weight percent. (Col. 4, lines 10 –11; Col. 12, lines 1 – 7). *Thus, MacLaren teaches that the sustained release portion of his tablet should include more than twice as much wax as currently specified in Applicants' claims.* This is a big difference. It cannot reasonably be said

to be in the range of what one would consider to be an "obvious" modification of MacLaren's teaching.

In view of MacLaren's repeated urgings of the need to use a very high wax content in the sustained release portion of his tablet for a workable formulation, the mere fact that one example in Uemura happens to disclose a "single layer" tablet containing a relatively low amount of carnauba wax cannot reasonably be said to suggest use of small amounts of wax in a bilayer tablet. Given that MacLaren was only able to overcome alleged problems with making a satisfactory bilayer tablet by using such large amounts of carnauba wax, one of ordinary skill in the art trying to make a workable bilayer tablet formulation would not cavalierly ignore MacLaren's teachings and simply cut in half or more the amount of wax MacLaren found necessary for making a bilayer tablet. Doing so would go directly against the thrust of what MacLaren explicitly says is needed to make a workable a bilayer tablet composition.

MacLaren is a textbook case of a reference "teaching against" a direction taken by a later worker in this field.

Moreover, the purported combination of the MacLaren, Uemura, and Staniforth references would not have lead a person of ordinary skill in the art to formulate the sustained release portion of the bilayer tablet with from about 10 wt. % to about 60 wt. % of a cellulose binder, such as hydroxypropyl methylcellulose, and from about 5 wt. % to about 50 wt. % of ethylcellulose. Nothing suggests use of both materials in one layer, much less both materials in one layer in the amounts claimed.

Assuming *arguendo* that either Uemura or Staniforth might have led one of ordinary skill in the art to incorporate a cellulose derivative (either hydroxypropyl methylcellulose or ethylcellulose) in one of the layers of a bilayer tablet, nothing in these references would have suggested using both cellulose derivatives in the same layer. Since nothing in these references would suggest using both materials at one time in the same layer, then a fortiori nothing would suggest using both materials in the same layer in the specific weight percentages specified in the current claims.

In mentioning the possible use of hydroxypropyl methylcellulose or ethylcellulose, respectively, in a single layer tablet, Uemura and Staniforth simply propose an "either, or" scenario of alternative excipients. At most, one of ordinary skill hypothetically "might" have chosen to use one of these cellulose derivative binders, but absolutely nothing in the references

would have motivated a person of ordinary skill to use both distinctly different materials in combination in the same layer.

Again, even if Uemura and Staniforth could somehow be said to have led one to use both cellulose derivatives together, which they cannot, the references still would not have led one of ordinary skill to use both of the cellulose derivatives in the amounts now specified in the Applicants' claims.

For at least the foregoing reasons, independent Claims 1, 18, 27, and 30 – 32, as well as their respective dependent claims, are both novel and nonbovious over the cited prior art references.

Finally, the Applicants reassert the patentability arguments presented in their previous amendment of July 15, 2008. Since the present amendments to the claims are narrowing in nature, the previously presented patentability arguments are still applicable with at least the same force with regard to the allowability of the claims in their current form. While these arguments have not been repeated in full herein, they are incorporated herein by reference and Applicants reserve the right to advance all of the patentability arguments from their July 15, 2008 amendment should an Appeal of this case be necessary.

In light of the foregoing, Applicants urge the Examiner to reconsider the application, to withdraw the rejections, and to issue a notice of allowance at the earliest possible convenience.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our Deposit Account No. 12-2355.

Respectfully submitted,

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